Attachment 1

TECHNICAL DATA

Phospholipon® 90 G

-Purified Phosphatidylcholine,	no other	phospholipid
impurities		

-Supported by US Drug Master File#16614 Canadian Drug Master File# 2004-010

Applications:

-Preparation of mixed micelles, liposomes and micro emulsions.

-Solubilizer for parenteral administration forms

-Emulsifier for pharmacy, dermatology and cosmetics

-Phosphatidylcholine source for drugs and dietetics.

Characteristics **

Identity

conforms

to reference spectra

Properties pale yellow, to yellow

granular material

Moisture

NMT 1.5 %

Acid value

NMT 0.5

Residual solvents

-Ethanol

NMT 0.2 %

-Ethylmethylketone

NMT 500 ppm NMT 5

Peroxide value
Toluene insoluble matter

NMT 0.05 %

Assay Phospholipids

-Phosphatidylcholine

Minimum 94.0 % NMT 4.0 %

-Lysophosphatidylcholine Tocopherol

NM1 4.0 % NMT 0.3 %

Microbiological purity

-Aerobic total count

NMT 100 germs /1g NMT 10 germs / 1g

-Fungi

-Enterobacteria and certain other

gram-neg, bacteria

absent in 1g

-Pseudomonas aeruginosa

absent in 1g absent in 1g

-Staphylococcus aureus -Bacterial endotoxins

NMT 10 EU / 1g

**Method descriptions are available upon request.

Packaging:

10kg welded in aluminum PE-foil under inert gas. 1kg welded in aluminum PE-foil under inert gas

Storage:

Under dry conditions at max. temperature of 8°C sealed

under inert gas.